

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

JANSSEN PHARMACEUTICA, N.V., )  
Plaintiff, )  
v. )  
DAVID J. KAPPOS, et al., )  
Defendants. )

1:11cv969 (LMB/IDD)



MEMORANDUM OPINION

Plaintiff Janssen Pharmaceutica, N.V. ("Janssen"), a Belgian corporation that is the assignee of U.S. Patent No. 7,741,356 ("the patent" or "the '356 patent"), has sued the United States Patent and Trademark Office and its director, David J. Kappos, seeking a 98-day increase to the term of the '356 patent ("patent term" or "PTA"). Before the Court is defendants' Motion to Dismiss, in which they argue that the Court does not have jurisdiction over this action, because when the complaint was filed on September 9, 2011, the applicable statute, 35 U.S.C. § 154(b)(4)(A), vested exclusive jurisdiction over such actions in the United States District Court for the District of Columbia.<sup>1</sup> Defendants also argue that under the same

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<sup>1</sup> On September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), which replaced the United States District Court for the Eastern District of Virginia as the exclusive venue for civil actions brought under 35 U.S.C. § 154(b)(4)(A). The

statute plaintiff's claim is barred by the applicable statute of limitations. For the reasons discussed below, defendants' motion will be granted to the extent that this civil action will be transferred to the United States District Court for the District of Columbia.

## I. BACKGROUND

### A. Statutory and Regulatory Context

After a patent application is submitted, a patent examiner with the United States Patent and Trademark Office ("USPTO") determines whether the asserted invention meets the requirements for patentability. If the patent examiner determines that the invention in the application is entitled to patent protection, the USPTO sends the applicant a notice of allowance. The notice of allowance specifies the required issue fee, which must be paid within three months of issuance of the notice. 37 C.F.R. § 1.311; Manual of Patent Examining Procedure ("MPEP") § 1.311. The notice of allowance also includes the USPTO's calculation of the patent term adjustment, that is, the time period for which the patent will remain in effect. See 35 U.S.C. § 154(b)(3)(B)(i). Once the issue fee is timely paid, the USPTO will issue the patent. MPEP § 1.314.

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amended provision applies "to any civil action commenced on or after" September 16, 2011. See id. § 9(b).

Under the current version of the patent statute, a patent's term is limited to 20 years, measured from the date the patent application is filed with the USPTO. 35 U.S.C. § 154(a)(2). The number of days during which an application is pending in the USPTO will therefore decrease the patent's ultimate term. To address the concern that the duration of a patent could be significantly shortened due to administrative delay, 35 U.S.C. § 154(b) provides that the term of a patent may be adjusted to account for various delays that occur between the time a patent application is filed and when the patent is ultimately issued. Among other adjustments, 35 U.S.C. § 154(b)(1)(A) provides for a day-for-day extension of a patent term for each day that the USPTO does not provide a notification pursuant to 35 U.S.C. § 132 or a notice of allowance under § 151, beyond fourteen months from the date the patent application was filed. This delay is known as "A Delay." Subsection (1)(B) provides for a patent term adjustment when a patent issuance is delayed due to the USPTO's failure to issue a patent within three years of the application being filed ("B Delay").<sup>2</sup>

The Director must "prescribe regulations establishing procedures for the application for and determination of patent

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<sup>2</sup> See Wyeth v. Kappos, 591 F.3d 1364, 1367 (Fed. Cir. 2010) for a summary of the types of delay underlying patent term adjustments.

term adjustments." 35 U.S.C. § 154(b)(3)(A). Pursuant to such procedures, the Director shall

- (i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application under section 151; and
- (ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

Id. § 154(b)(3)(B). The regulations promulgated by the USPTO provide that "[a]ny request for reconsideration of the patent term adjustment indicated in the notice of allowance, except as provided in paragraph (d)...must be by way of an application for patent term adjustment." 37 C.F.R. § 1.705(b). The request must be filed no later than the date when the applicant pays the issue fee, which is due no later than three months from the notice of allowance. Id.; Pl.'s Opp'n Ex. 1 (MPEP § 1306, regarding timing of issue fee). A patentee may also seek reconsideration of a revised patent term adjustment that is reflected in the patent itself, or a revision that should have been reflected in the patent, within two months of the date the patent issued. 37 C.F.R. § 1.705(d). Such a request will be considered untimely as to issues that were raised or could have been raised before the patent issued. Id.

Under the statute, "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a

patent term adjustment under the procedures established under this subsection [§ 154(b)(3)], notwithstanding any appeal taken by the applicant of such determination." 35 U.S.C.

§ 154(b)(3)(D). The statute also sets forth the mechanism under which "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3)" may seek judicial review.

Section 154(b)(4)(A) states that such an applicant

shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 [the Administrative Procedure Act], shall apply to such action.<sup>3</sup>

B. Factual Background

Patent Application No. 11/079,647, which ultimately issued as the '356 patent, was filed on March 14, 2005. The USPTO issued its first office action concerning the application on April 9, 2007. That office action was rescinded and replaced by a different office action on July 16, 2007. See Pl.'s Opp'n Ex. 3 (July 16, 2007 office action). Both the first and second office actions occurred more than 14 months after the application was filed, entitling the applicant to an extension of the patent term for A Delay. When the USPTO mailed the applicant a notice of allowance on October 14, 2008, the notice

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<sup>3</sup> See supra note 1 (explaining the amendments to the patent statute and the applicability of the pre-amendment venue provision).

stated that the application would receive 207 days of PTA, based on the April 9, 2007 date of the first office action. Compl. ¶ 12. Had the July 16, 2007 "rescind and replace" date been used, the applicant would have received 98 additional days of PTA.

See Compl. Ex. B.

On January 13, 2009, after receiving the notice of allowance but before the patent issued, plaintiff submitted its first Request for Reconsideration pursuant to 37 C.F.R. § 1.705(b), in which it argued that the PTA calculation should have been based on the July 16, 2007 "rescind and replace" office action and, accordingly, the patent term should be extended by an additional 98 days due to A Delay. See Compl. Ex. B. The USPTO dismissed plaintiff's Request for Reconsideration on May 18, 2010 ("Decision I"), explaining that

the subsequent mailing of a communication by the examiner altering the previous action does not negate the fact that the Office took action in this application within the meaning of § 1.702(a)(1) on April 9, 2007. The examiner does not have the authority to vacate, rescind, or withdraw an Office action. Unless vacated by the Technology Center Director, for purposes of calculating patent term adjustment, the action originally mailed by the examiner on April 9, 2007 will be used to calculate the amount of Office delay.

Compl. Ex. C at 3. The '356 Patent was issued on June 22, 2010, reflecting a total PTA of 1009 days, including 330 days of USPTO

"A Delay" based on the April 9, 2007 first office action. Id. ¶ 15.<sup>4</sup>

On July 19, 2010, plaintiff filed a petition pursuant to 37 C.F.R. § 1.181 ("Rule 181 Petition"), seeking review of Decision I by the Director and again arguing that the patent term should be extended by an additional 98 days due to A Delay. See Compl. Ex. D. The Rule 181 Petition was dismissed on March 15, 2011 ("Decision II") in an opinion issued by a senior USPTO attorney. See Compl. Ex. E. The USPTO explained that

[t]he fact that the Office later set aside the restriction requirement of April 9, 2007 does not negate the fact that the Office responded within the meaning of 35 U.S.C. § 154(b)(1)(A)(i) and 37 CFR 1.702(a)(1) on April 9, 2007. Unless expunged from the record (which is not warranted in this situation), for purposes of calculating patent term adjustment, the Office action entered by the examiner on April 9, 2007 was properly used to determine whether the USPTO delayed the issuance of the above-identified patent by failing to provide a notification under 35 U.S.C. § 132 within 14 months after the date on which the application was filed....

Id. Plaintiff sought reconsideration of Decision II on April 15, 2011. The USPTO denied reconsideration on September 6, 2011 ("Decision III"). See Compl. Exs. F, G. Decision III stated that it was "a final agency action within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review."

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<sup>4</sup> The 1009 days of PTA includes various calculations for delay not at issue in this litigation. The only issue before this Court is whether 98 additional days of PTA for A Delay should have been allowed based on the July 16, 2007 office action as the first office action. See Compl. ¶ 28.

Compl. Ex. G at 1 n.1. In Decision III, the USPTO adhered to its reasoning in Decision II, holding that

the vacatur of an Office action does not signify that the vacated Office action is void ab initio and is to be treated as if the USPTO had never issued the Office action.

Id. at 5. Plaintiff filed the complaint in this action on September 9, 2011, once again seeking a 98-day increase to the patent's term. Compl. ¶¶ 22, 27.

## II. DISCUSSION

### A. Standard of Review

Federal district courts are courts of limited subject matter jurisdiction and possess only the jurisdiction granted to them by the United States Constitution and by federal statutes.

Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 552 (2005) (citing Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994)). Pursuant to Fed. R. Civ. P. 12(b)(1), the plaintiff must show by a preponderance of the evidence that jurisdiction is proper in this Court. See United States ex rel. Vuyyuru v. Jadhav, 555 F.3d 337, 347-48 (4th Cir. 2008); Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982).

### B. Applicability of 35 U.S.C. § 154(b)(4)(A)

Defendants argue that this action must be dismissed because plaintiff has not complied with the requirements of 35 U.S.C. § 154(b)(4)(A), namely, that this action when it was filed could only be brought in the United States District Court for the

District of Columbia. Defendants also argue that the Court should dismiss the complaint rather than transfer it to the District of Columbia because as a matter of law the complaint is time-barred under § 154(b)(4)(A). Plaintiff responds that the venue and timing requirements of § 154(b)(4)(A) do not apply because it seeks review of the USPTO's PTA determination under the procedures set forth in the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706.<sup>5</sup>

At the heart of this dispute is the question of whether the specific venue and limitations period contained in the patent statute govern this complaint or whether the more general venue and timing provisions of the APA apply. To resolve this question, the two statutes must first be construed. "As always, the starting point in every case involving construction of a statute is the language itself." Wyeth v. Kappos, 591 F.3d 1364, 1369 (Fed. Cir. 2010) (quoting United States v. Hohri, 482 U.S. 64, 68 (1987)) (internal quotation marks omitted). On its face, § 154(b)(4)(A) applies to all PTA decisions made by the Director applying the USPTO's own regulations before issuance of a patent. See id. ("An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the

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<sup>5</sup> Defendant agrees that, if the APA controls, plaintiff's complaint was timely filed. Defs.' Reply at 11.

United States District Court for the District of Columbia within 180 days after the grant of the patent.”). Plaintiff argues that § 154(b)(4)(A) only applies to USPTO determinations made before a patent is issued and, as such, its limitations are inapplicable in a case where, as here, the USPTO’s final PTA decision was made after the patent was issued. Plaintiff supports its position by pointing to language in § 154(b)(4)(A) which states that the provision applies to “determination[s] made by the Director under paragraph (3).” Plaintiff argues that paragraph (3) applies only to determinations that occur before the patent is granted. Specifically, paragraph (3) instructs the Director to make a PTA determination, “transmit a notice of that determination with the written notice of allowance,” and “provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.” It further requires that the Director “proceed to grant the patent after completion of the Director’s determination of a patent term adjustment...notwithstanding any appeal taken by the applicant of such a determination.”

Here, the USPTO rendered Decision III considerably after the patent was issued pursuant to administrative review procedures not mandated by § 154(b)(3). The USPTO’s rules expressly contemplate that an agency decision on a request for

reconsideration can be made after a patent issues. For example, under 37 C.F.R. § 1.705(d),

If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued....

Furthermore, 37 C.F.R. § 1.181 provides that a "[p]etition may be taken to the Director" to "invoke the supervisory authority of the Director in appropriate circumstances." Under either provision, an agency may issue its decision after the patent's issuance and, in plaintiff's view, such administrative review that occurs after issuance is not a "determination made by the Director under paragraph (3)" and therefore § 154(b)(4)(A)'s restrictions do not apply.

Defendants agree that paragraph (3) refers to pre-issuance procedures, see Defs.' Reply at 3, but persuasively argue that the USPTO's determination as to the appropriate amount of PTA—whether made pursuant to mandatory pre-issuance procedures or optional post-issuance review—is a single question subject to the forum and timing limitations of § 154(b)(4)(A). The Court agrees and holds that, in a case in which a patentee is challenging the number of days of PTA calculated by the USPTO, whether that calculation occurred before the patent was issued

or afterwards, such a decision is governed by §§ 154(b)(3) and (b)(4)(A). In other words, any challenge to a PTA determination is governed by § 154(b)(4)(A).

To accept plaintiff's argument, that the availability of post-issuance administrative review frees the corresponding USPTO determination from the strictures of § 154(b)(4)(A), would eviscerate the very limitations on judicial review Congress included in the patent statute. Under plaintiff's interpretation, a patentee could pursue multiple rounds of lengthy post-issuance administrative review, with the result of side-stepping the exclusive forum requirement and the short statute of limitations prescribed by Congress in the patent statute.<sup>6</sup> Such results are entirely inconsistent with the Congressional intent plain on the face of the statute—to strictly limit the forum and timing for seeking judicial review of these very specific USPTO decisions. For these reasons, the Court agrees with defendants' contention that it would be absurd for Congress to "impose limitations on the specific statutory judicial review mechanisms (*i.e.*, § 154(b)(4)(A)) when it simultaneously intended to allow a patentee to seek generic APA review of the very same question, (*i.e.*, the number of days of

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<sup>6</sup> In contrast to the 180-day limitations period of § 154(b)(4)(A), actions brought under the APA are subject to a six-year statute of limitations. 28 U.S.C. § 2401(a).

PTA to which the '356 patent is entitled) without any of those same restrictions." Defs.' Reply at 5 (emphasis in original).

Defendants also argue that the venue and timing requirements in § 154(b)(4)(A) preempt generic APA remedies, whereas plaintiff maintains that the two remedial structures can co-exist. Defendants cite extensive authority to support their argument that "a precisely drawn, detailed statute pre-empts more general remedies." Defs.' Mem. at 12 (quoting Brown v. GSA, 425 U.S. 830, 834 (1976)). In Block v. North Dakota, 461 U.S. 273 (1983), the Supreme Court easily dismissed the argument that the general remedy of an officer's suit could be used in lieu of a specific statutory scheme that included a statute of limitations and other restrictions. The Court explained that if it adopted the contrary view, "all of the carefully crafted provisions of the [Quiet Title Act] deemed necessary for the protection of the national public interest could be averted. It would require the suspension of disbelief to ascribe to Congress the design to allow its careful and thorough remedial scheme to be circumvented by artful pleading." Block, 461 U.S. at 284-85 (quoting Brown v. GSA, 425 U.S. 820, 833 (1976)) (internal quotation marks omitted). Preemption of a general remedy by a tailored one is especially appropriate "when resort to a general remedy would effectively extend the limitations period for the

specific one." EC Term of Years Trust v. United States, 550 U.S. 429, 434 (2007).

Defendants also point to Franchi v. Manbeck, 972 F.2d 1283 (Fed. Cir. 1992), in which the Federal Circuit addressed another provision of the Patent Act, 35 U.S.C. § 32. At the time, § 32 required all actions challenging a USPTO decision regarding suspension or exclusion from the Patent Bar to be brought in the United States District Court for the District of Columbia, "under such conditions and upon such proceedings as it by its rules determines." That court's rules required such a petition to be filed within thirty days of the issuance of the challenged order. See Franchi, 972 F.2d at 1288, 1289 n.7 (quoting D.C. Ct. R. Ann. 213). The Franchi Court held that the District of Columbia court was the exclusive forum for review of a USPTO decision taken under § 32 and accordingly, a plaintiff could not file a general mandamus action in another district court after the thirty-day filing period expired, characterizing such action as "an attempt to subvert the orderly administrative mechanism for review of the Commissioner's decision under 35 U.S.C. § 32." Id. at 1288 (internal quotation marks omitted).

Plaintiff contests defendants' reliance on Franchi and Block, arguing that neither case involved motions for reconsideration nor did the plaintiffs in those cases seek reconsideration before the expiration of the filing period.

Pl.'s Opp'n at 13-14. That procedural difference does not make the reasoning of those cases inapplicable. The relevant question here is whether a specific statutory scheme such as that prescribed in § 154(b)(4)(A) is exclusive and supplants generic APA procedures, or whether plaintiff may still resort to the more generous provisions applicable to APA challenges so as to avoid the patent statute's restrictions. The simple answer is that the exclusivity question is unaffected by the status of a request for reconsideration.

By its own terms, the APA does not apply "to the extent that...statutes preclude judicial review." 5 U.S.C. § 701(a)(1); see also *id.* § 702 ("Nothing herein...affects other limitations on judicial review" or "confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought"). As defendants correctly argue, § 154(b)(4)(A) itself incorporates elements of the APA by specifying that the APA applies to civil actions brought in district court under that section. Importantly, however, § 154(b)(4)(A) references the APA in the context of the patent statute's specific forum requirement and 180-day statute of limitations, clearly indicating that these specific requirements supplant the more generous provisions applicable to general APA challenges. The Court therefore reads § 154(b)(4)(A) as establishing a 180-day statute of limitations

beginning from the date a patent issues, regardless of whether any request for reconsideration of PTA is pending before the USPTO, and exclusive venue in the United States District Court for the District of Columbia for complaints filed before September 16, 2011, and in this district for complaints filed on or after September 16, 2011. By referencing the APA, the patent statute provides that the APA will govern all other aspects of the district court's review of a PTA determination including, for example, the standard of review to be applied and the deference owed to the agency. This reading allows the two statutes to co-exist while respecting the strict time and venue limitations of the patent statute specifically tailored to review of PTA determinations.<sup>7</sup>

Plaintiff has not shown a "good countervailing reason" for the Court to decline to apply "the better fitted statute" in this action. EC Term of Years Trust, 550 U.S. at 434. For these reasons, the Court holds that plaintiff cannot avoid the venue and timing requirements of § 154(b)(4)(A) by resorting to the APA and, as such, this action cannot go forward in this

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<sup>7</sup> Section 154(b)(4)(A)'s explicit reference to and incorporation of the APA completely undermines plaintiff's argument that defendants' reading repeals the APA by implication. The patent statute merely imposes an exclusive forum requirement and a statute of limitations on civil actions that, in all other respects, must proceed pursuant to APA procedures.

district because it could only have been brought in the United States District Court for the District of Columbia.

C. Transfer to the United States District Court for the District of Columbia

Recognizing that if § 154(b)(4)(A) is found to apply, it has filed this civil action in the wrong district, plaintiff requests that the complaint be transferred to the United States District Court for the District of Columbia. When a court finds that it lacks jurisdiction, "in the interest of justice" it may transfer an action "to any other such court in which the action or appeal could have been brought at the time it was filed or noticed..." 28 U.S.C. § 1631. As discussed above, in addition to requiring that this civil action be brought in the District of Columbia, § 154(b)(4)(A) also requires that a patentee file its civil action within 180 days of the issuance of the patent. Because the patent was issued on June 22, 2010, this lawsuit, commenced on September 9, 2011, is clearly time-barred unless the 180-days-from-issuance statute of limitations is tolled.

Relying on Interstate Commerce Commission v. Brotherhood of Locomotive Engineers, 482 U.S. 270 (1987), which holds that if a timely request for reconsideration is presented to the administrative agency, the statute of limitations for seeking judicial review does not begin to run until the request is

decided by the agency,<sup>8</sup> plaintiff asserts that its complaint is timely because it was filed within 180 days of the USPTO's Decision II. Pl.'s Opp'n at 19-20.<sup>9</sup> During oral argument and in their pleadings, defendants argue that Locomotive Engineers does not apply to actions brought under § 154(b)(4)(A), primarily because the statute of limitations begins to run from the date the patent is issued, not from the date of the agency's final PTA determination.

After oral argument on the pending motion, the United States District Court for the District of Columbia ruled in another action that tolling does apply to actions brought under § 154(b)(4)(A). See Bristol-Myers Squibb Co. v. Kappos, Civ. No. 09-1330 (EGS) (D.D.C. Jan. 27, 2012). Under that precedent, the complaint in this action may have been timely filed. Without expressing an opinion as to whether this Court would

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<sup>8</sup> Technically, the Locomotive Engineers holding, which describes when a statute of limitations starts to run, does not actually provide for tolling a statute of limitations. See Cochran v. Holder, 564 F.3d 318, 321 n.2. However, the Court will use the terminology of the Supreme Court, see Stone v. INS, 514 U.S. 386, 392 (1995), and the United States District Court for the District of Columbia, see Bristol-Myers Squibb Co. v. Kappos, Civ. No. 09-1330 (EGS) (D.D.C. Jan. 27, 2012), and refer to it as a "tolling" decision.

<sup>9</sup> It is unclear why plaintiff relies on Decision II instead of Decision III as the date from which the statute of limitations began to run. Nevertheless, because Decision II was issued on March 15, 2011, more than 180 days after the patent issued, the Locomotive Engineers ruling would have to apply for the complaint to be timely filed.

find that the 180-day statute of limitations starts when all administrative review is complete or can otherwise be tolled, the Bristol-Myers decision provides a sufficient basis upon which to transfer this action to the United States District Court for the District of Columbia.

### III. CONCLUSION

For the foregoing reasons, the Court finds that the challenged USPTO decision is governed by 35 U.S.C. § 154(b)(4)(A) and, as a result, this action had to have been brought in the United States District Court for the District of Columbia. Accordingly, defendants' motion to dismiss this complaint will be granted as to the improper venue argument and denied without prejudice as to the argument that the complaint is time-barred, and this civil action will be transferred to the District of Columbia court by an Order to accompany this Memorandum Opinion.

Entered this 10<sup>th</sup> day of February, 2012.

Alexandria, Virginia

  
/s/  
Leonie M. Brinkema  
United States District Judge